

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

TIMOTHY GIESER,

Plaintiff,

v.

MODERNA CORP.,

Defendant.

Case No. 1:24-cv-00458-JLT-CDB

FINDINGS AND RECOMMENDATIONS TO
GRANT DEFENDANT’S MOTION TO DISMISS
WITH PREJUDICE

(Doc. 5)

21-DAY DEADLINE

Pending before the Court is the motion of Defendant Moderna Corp. (“Defendant”) to dismiss Plaintiff Timothy Gieser’s (“Plaintiff”) complaint. (Doc. 5).¹ Plaintiff did not file an opposition to Defendant’s motion, and the time to do so has passed.² On May 10, 2024, the Honorable District Judge Jennifer L. Thurston referred the pending motion to the Undersigned, pursuant to 18 U.S.C. § 636(b)(1)(B) and E.D. Cal. Local Rule 304(a). (Doc. 7). For the reasons set forth herein, the

¹ Moderna US, Inc. is erroneously named in Plaintiff’s complaint as Moderna Corp. (Doc. 1 at n.1).

² Plaintiff’s failure to file an opposition to Defendant’s motion is construed as a non-opposition to dismissal. *See* Local Rule 230(c) (“A failure to file a timely opposition may also be construed by the Court as a non-opposition to the motion.”).

Undersigned will recommend Defendant's motion to dismiss be granted and Plaintiff's complaint be dismissed with prejudice.

Background

On March 10, 2020, the Secretary of the Department of Health and Human Services ("HHS") issued a declaration under the Public Readiness and Emergency Preparedness Act ("PREP Act") stating that the 2019 coronavirus disease ("COVID-19") was a public health emergency and that medical countermeasure against COVID-19 were required. (Doc. 6-1 at 69-74).³ The HHS Secretary would later amend the March 10, 2020, declaration to include COVID-19 vaccines as a medical countermeasure under the PREP Act. *Id.* at 80-88.

On December 18, 2020, the U.S. Food and Drug Administration ("FDA") issued an emergency use authorization ("EUA") for a second vaccine for the prevention of COVID-19. (Doc. 6-1 at 2). The vaccine has been known as the Moderna COVID-19 vaccine. *Id.* at 1, 44. The EUA allowed the Moderna COVID-19 vaccine to be distributed in the United States for use in individuals 18 years of age and older. *Id.*

In 2021, Plaintiff was incarcerated at Wasco State Prison. (Doc. 1-1 at 6-7). On February 7, 2021, Plaintiff received the first dose of the Moderna COVID-19 vaccine. *Id.* On February 25, 2021, Plaintiff saw an optometrist and underwent an eye exam to be fit for eyeglasses. *Id.* Plaintiff states the optometrist identified no issues with his eyes other than needing glasses. *Id.*

On March 3, 2021, Plaintiff received a second dose of the Moderna COVID-19 vaccine. *Id.* at 6-7. The following day, Plaintiff claims he experienced a loss of "more than 50%" of his vision in his right eye and requested medical assistance. *Id.* at 7. On March 8, 2021, a licensed vocational nurse provided Plaintiff with eye drops. *Id.* The next day, Plaintiff submitted another medical request for assistance "as [his] vision was not improving." *Id.* Plaintiff saw onsite doctors and continued to request further medical assistance on March 12 and 15, 2021. *Id.*

On March 25, 2021, Plaintiff saw an optometrist who determined Plaintiff had a "retina detachment." *Id.* at 6, 8. The optometrist referred Plaintiff to a "private [doctor], Dr. Tawansy. *Id.*

³ As addressed below, Defendant requests the Court take judicial notice of certain exhibits not attached to Plaintiff's complaint.

1 On March 26, 2022, Dr. Tawansy examined Plaintiff's right eye and "ordered eye surgery." *Id.* at 8.
2 Plaintiff underwent laser surgery on his right eye for a "tear" on March 29, 2021. *Id.* On April 14,
3 2021, Plaintiff had a follow-up examination with Dr. Tawansy. *Id.* Dr. Tawansy diagnosed Plaintiff
4 with "[r]ight eye Retinal Detachment as well as cataracts [d]eveloping." *Id.*

5 At some point, Plaintiff was transferred to San Quentin State Prison. *Id.* at 3. On January 31,
6 2022, the FDA granted the Moderna COVID-19 vaccine full approval. (Doc. 6-1 at 44). That same
7 day, Plaintiff filed the operative complaint to the Kern County Superior Court. (Doc. 1-1). Plaintiff
8 raises a claim for products liability against Defendant and seeks compensatory and punitive damages
9 in the amount of \$1,500,000. *Id.* at 5.

10 On March 18, 2024, Defendant was served with the summons and complaint. (Docs. 1 at 2; 1-
11 2). Defendant removed the action to this Court on April 17, 2024. (Doc. 1). On April 24, 2024,
12 Defendant filed the instant motion to dismiss. (Doc. 5). Defendant contends Plaintiff's claim is
13 barred and pre-empted by the PREP Act. (Doc. 5-1 at 11-21). Defendant also argues Plaintiff has
14 failed to sufficiently plead a products liability claim. *Id.* at 21-22. Additionally, Defendant requests
15 the Court take judicial notice of documents related to its motion to dismiss. (Doc. 6). Plaintiff did not
16 file any response to Defendant's motion to dismiss or separate request of the Court to take judicial
17 notice of certain documents.

18 **Discussion**

19 **I. Request for Judicial Notice**

20 Fed. R. Evid. 201 permits a court to take judicial notice of any facts "generally known within
21 the trial court's territorial jurisdiction "or that "can be accurately and readily determined from sources
22 whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(2). A court "must take
23 judicial notice if a party requests it and the court is supplied with the necessary information." Fed. R.
24 Evid. 201(c). "Facts subject to judicial notice may be considered by a court on a motion to dismiss."
25 *Pruitt v. United States Bank, N.A.*, No. 1:13-cv-01198-AWI-SKO, 2013 WL 6798999, at *1 (E.D. Cal.
26 Dec/ 20, 2013) (citing *In re Russell*, 76 F.3d 242, 244 (9th Cir. 1996)); see *Indemnity Corp v.*
27 *Weisman*, 803 F.2d 500, 504 (9th Cir. 1986) (a court may take judicial notice of matters of public
28 record outside the pleadings).

Defendant requests that the Court take judicial notice of the following documents in support of its motion to dismiss:

(1) FDA Press Release: “FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine”, (2) FDA Fact Sheet for Healthcare Providers Administering Vaccine, (3) FDA Press Release, Coronavirus (COVID-19) Update: FDA Takes Key Action by Approving Second COVID-19 Vaccine, U.S. Food & Drug Admin., (4) U.S. Centers For Disease Control-COVID Data Tracker, (5) U.S. Centers for Disease Control-COVID-19 Vaccine Safety Monitoring Systems, (6) Congressional Research Service, “The PREP Act and COVID-19, Part 1: Statutory Authority to Limit Liability for Medical Countermeasures”, (7) Declaration Under the PREP Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198, 21012, and 79190, (8) U.S. Department of Health and Human Services, Advisory Opinion on the Public Readiness and Emergency Preparedness Act and March 10, 2020, Declaration Under the Act, at 1, and (9) Congressional Research Service, “The U.S. Government’s Role in Domestic and Global COVID-19 Vaccine Supply and Distribution: Frequently Asked Questions.”

(Doc. 6 at ¶¶ 1-9). The Court has examined Defendant’s proffered documents and finds they are suitable for judicial notice as a matter of public record that “can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.” *Eidson v. Medtronic, Inc.*, 981 F. Supp. 2d 868, 878-79 (N.D. Cal. 2013); *see Rice v. Kimberly-Clark Corp.*, No. 2:21-cv-01519-DAD-KJN, 2022 WL 16804522, at *3 (E.D. Cal. Nov. 8, 2022) (taking judicial notice of documents on the FDA website); *Lotus Vaping Techs., LLC v. U.S. FDA*, 73 F.4th 657 (9th Cir. 2023) (taking judicial notice of FDA press releases); *Johnson v. Ashley Furniture Indus.*, No. 13-cv-2445-BTM-DHB, 2014 WL 6892173, at *2 (S.D. Cal. Nov. 4, 2014) (taking notice of Congressional Research Service reports); *Cent. Cal. Env’t Just. Network v. Randolph*, No. 2:22-cv-01714-DJC-CKD, 2023 WL 4678991, at *6 (“the United States Code clearly states that ‘[t]he contents of the Federal Register shall be judicially noticed...’”) (quoting 44 U.S.C. § 1507)); *United States v. Orozco Acosta*, 607 F.3d 1156, 1164 n.5 (9th Cir. 2010) (taking judicial notice of summary on government web site of government-compiled statistics). Therefore, this Court shall recommend Defendant’s request for judicial notice be GRANTED. The Court identifies below facts within the proffered documents it concludes may be “accurately and readily determinable” and subject to judicial notice. *See Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 999 (9th Cir. 2018).

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1 II. Motion to Dismiss

2 A. Legal Standard

3 Rule 12(b)(1) of the Federal Rules of Civil Procedure allows a defendant to move for dismissal
4 on the basis that the court lacks jurisdiction over the subject matter of the action. *See* Fed. R. Civ. P.
5 12(b)(1). The burden is on the plaintiff to establish that the court has subject matter jurisdiction over
6 the action. *See Assoc. of Med. Colls. v. United States*, 217 F.3d 770, 778-79 (9th Cir. 2000).

7 A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) asks a court to dismiss a
8 plaintiff's complaint for failing "to state a claim upon which relief can be granted." Fed. R. Civ. P.
9 12(b)(6). Such a motion tests the complaint's sufficiency. *N. Star Int'l v. Ariz. Corp. Comm'n*, 720
10 F.2d 578, 581 (9th Cir. 1983) (citing *Peck v. Hoff*, 660 F.2d 371, 374 (8th Cir. 1981)). A complaint
11 may be dismissed as a matter of law either for lack of a cognizable legal theory or the absence of
12 sufficient facts alleged under a cognizable legal theory. *Balistreri v. Pacifica Police Dep't*, 901 F.2d
13 696, 699 (9th Cir. 1990) (citing *Robertson v. Dean Witter Reynolds, Inc.*, 749 F.2d 530, 533-34 (9th
14 Cir. 1984)). To survive a motion to dismiss under Rule 12(b)(6), a complaint must provide sufficient
15 factual matter to state a claim to relief that is plausible on its face. *Ashcroft v. Iqbal*, 556 U.S. 662,
16 678 (2009); *see* Fed. R. Civ. P. 8(a)(2) (a complaint must contain a short and plain statement of the
17 claim showing that the pleader is entitled to relief). A complaint satisfies the plausibility requirement
18 if it contains sufficient facts for the court to "draw [a] reasonable inference that the defendant is liable
19 for the misconduct alleged." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

20 When considering a Rule 12(b)(6) motion to dismiss for failure to state a claim, the court
21 must accept as true all allegations put forth in the complaint and construe all facts and inferences in
22 favor of the non-moving party. *Erickson v. Pardus*, 551 U.S. 89, 94 (2007) (citations omitted); *Hebbe*
23 *v. Pliler*, 627 F.3d 338, 340 (9th Cir. 2010). The complaint need not include "detailed factual
24 allegations," but must include "more than an unadorned, the-defendant-unlawfully-harmed-me
25 accusation." *Iqbal*, 556 U.S. at 678 (citations omitted). The Court is "not required to accept as true
26 allegations that contradict exhibits attached to the Complaint or matters properly subject to judicial
27 notice, or allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable
28

1 inferences.” *Seven Arts Filmed Entm’t, Ltd. v. Content Media Corp. PLC*, 733 F.3d 1251, 1254 (9th
2 Cir. 2013) (quoting *Daniels-Hall v. Nat’l Educ. Ass’n*, 629 F.3d 992, 998 (9th Cir. 2010)).

3 Pro se pleadings are held to a less stringent standard than those drafted by lawyers. *Haines v.*
4 *Kerner*, 404 U.S. 519, 520 (1972). Pro se complaints are construed liberally and may only be
5 dismissed if it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim
6 which would entitle him to relief. *Nordstrom v. Ryan*, 762 F.3d 903, 908 (9th Cir. 2014). A pro se
7 litigant is entitled to notice of the deficiencies in the complaint and an opportunity to amend unless the
8 complaint’s deficiencies cannot be cured by amendment. *Broughton v. Cutter Laboratories*, 622 F.2d
9 458, 460 (9th Cir. 1980) (per curiam).

10 B. Discussion

11 Defendant asserts Plaintiff’s claim is barred by the PREP Act. (Doc. 5-1 at 11-17). The PREP
12 Act, codified in Title 42 of the United States Code, “empowers the Secretary of [HHS] to deem an
13 event a ‘public health emergency’ and then take action to utilize funds established by the Treasury to
14 manage the emergency.” *Goins v. Saint Elizabeth Med. Ctr.*, 640 F. Supp. 3d 745, 752 (E.D. Ky.
15 2022) (citation omitted). The PREP Act also provides federal tort immunity from liability for
16 “covered persons” taking part in “covered countermeasures” to ensure that the government can act
17 swiftly in response to an emergency—specifically, a pandemic. *Id.*; *Maney v. Brown*, 91 F.4th 1296,
18 12988 (9th Cir. 2024). The law provides:

19 “[A] covered person shall be immune from suit and liability under federal and state law with
20 respect to all claims for loss caused by, arising out of, relating to, or resulting from the
21 administration to or the use by an individual of a covered countermeasure if a declaration...has
22 been issued with respect to such countermeasure.”

23 42 U.S.C. § 247d-6d(a)(1). “Covered countermeasures” includes products used to mitigate, prevent,
24 or limit the harm of a pandemic or epidemic. §§ 247d-6d(i)(1), (7). “Covered persons” includes
25 entities that are manufacturers or distributors of covered countermeasures. § 247d-6d(i)(2). The Act
26 clarifies the “scope” of immunity as including:

27 “[A]ny claim for loss that has a causal relationship with the administration to or use by an
28 individual of a covered countermeasure, including a causal relationship with the design,
development, clinical testing or investigation, manufacture, labeling, distribution, formulation,
packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing,

administration, licensing, or use of such countermeasure.”

42 U.S.C. § 247d-6d(a)(2)(B). The “sole exception” to immunity is for an exclusive federal cause of action for injury “caused by willful misconduct” brought in the United States District Court for the District of Columbia. §§ 247d-6d(d), (e); *Cannon v. Watermark Ret. Cmtys., Inc.*, 45 F.4th 137, 147 (D.C. Cir. 2022).⁴ Otherwise, a “covered person” under the PREP Act is completely immune from suit for conduct relating to “covered countermeasures.”

As discussed above, on March 10, 2020, the HHS Secretary issued a declaration under the PREP Act for medical countermeasures against COVID-19. (Doc. 6-1 at 69); *see Hampton v. California*, 83 F.4th 754, 762 (9th Cir. 2023) (finding the Act’s immunity lies dormant until the HHS Secretary makes a declaration that the Act’s immunity is in effect). The Moderna COVID-19 vaccine unquestionably is a “covered countermeasure” under the PREP Act. (Doc. 6-1 at 80-88); *see Cabaniss v. Pfizer, Inc.*, No. 23-55297, 2024 WL 511872, at *1 (9th Cir. Feb. 9, 2024) (“the Pfizer COVID-19 vaccine allegedly administered to T.C. is a ‘[c]overed countermeasure’ under the PREP Act.”). And by the plain language of the statute, Defendant, as a manufacturer of the COVID-19 vaccine, a “covered countermeasure,” is a “covered person” under the Act. *See Caratini-Soto v. Puerto Rico*, No. 23-1111 (SCC), 2023 WL 11196890, at *6 (D.P.R. Dec. 28, 2023) (finding manufacturers of COVID-19 vaccines are “covered persons” under the statute).

Plaintiff asserts he suffered “loss of vision,” a retinal detachment, and damage to his right eye “after receiving the second dose of the vaccine made by Moderna.” (Doc. 1-1 at 5-6). Plaintiff’s claim for loss relates to a covered countermeasure (administration of Defendant’s vaccine). Therefore, the Undersigned concludes that the PREP Act immunizes Defendant from Plaintiff’s claim. *Cf. T. C.*, 2022 WL 17578871, at *2 (“Plaintiff’s [c]omplaint alleges that his injury resulted from his use of a COVID-19 vaccine manufactured by Defendant. The Court concludes that Defendant is facially immune from suit in this Court under the PREP Act.”); *Caratini-Soto*, 2023 WL 11196890, at *6 (same).

⁴ The PREP Act further provides for a no-fault compensation program for eligible individuals. 42 U.S.C. § 247d-6e(a); *Goins*, 640 F. Supp. 3d at 752; *T.C. v. Pfizer, Inc.*, No. 22-cv-01242-WQH-AHG, 2022 WL 17578871, at *2, n.2 (S.D. Cal. Nov. 9, 2022).

Defendant contends the willful misconduct exception does not apply in this case. The Undersigned agrees. First, Plaintiff does not allege Defendant engaged in willful misconduct in his complaint (Doc. 1-1) and he failed to meet the PREP Act’s heightened pleading requirements for a willful misconduct claim. *See* 42 U.S.C. § 247d-6d(e)(3). Next, Plaintiff failed to file an affidavit from a non-treating physician or “certified medical records” to plead a willful misconduct claim under the PREP Act. § 247d-6d(e)(4), (C). Plaintiff has also failed to show he exhausted administrative remedies to raise a willful misconduct claim. § 247d-6e(a), (d)(1). Additionally, even if Plaintiff sufficiently alleged a willful misconduct claim, he cannot pursue a willful misconduct claim in this Court. Instead, such claims must be filed and maintained only in the United States District Court for the District of Columbia. 42 U.S.C. § 247d-6d(e)(1); *Perez v. Oxford Univ.*, No. 21-cv-4844 (VEC) (RWL), 2022 WL 1446543, at *6 (S.D.N.Y. Apr. 11, 2022), report and recommendation adopted by 2022 WL 1468438 (May 10, 2022).

Defendant also asserts Plaintiff’s claims are pre-empted. The PREP Act contains an express preemption clause that provides, “no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that...is different from, or is conflict with, any requirement [.]” 42 U.S.C. § 247d-6d(b)(8)(A). The PREP Act’s preemption clause provides a federal defense to state law claims. *See Saldana v. Glenhaven Healthcare*, 27 F.4th 679, 688 (9th Cir. 2022) (“the PREP Act is not a complete preemption statute.”); *Goins*, 640 F. Supp. 3d at 753 (citation omitted).

Here, Plaintiff raises a state law claim, products liability, against Defendant based on conduct related to its development and manufacture of the Moderna COVID-19 vaccine. (Doc. 1-1 at 5). Thus, Plaintiff’s state claim is fundamentally in conflict with the PREP Act’s immunity and exclusive remedy provisions, and therefore, is expressly preempted by the Act. 42 U.S.C. § 247d-6d(b)(8).

Separately, Defendant argues Plaintiff failed to state a claim for products liability under California law. (Doc. 5-1 at 21-22). Plaintiff’s complaint fails to indicate whether he is pursuing a products liability claim under a theory of negligence or strict liability. *See generally* (Doc. 1-1). To prove negligence under California law, a plaintiff must show that the defendant “had a duty to use due care, that he breached that duty, and that the breach was a proximate or legal cause of the resulting

injury.” *Nally v. Grace Cmty. Church*, 47 Cal. 3d 278, 253 (Cal. 1988). In the products liability context, the plaintiff must demonstrate that a defect in the defendant’s product caused injury and the existence of the defect was due to the defendant’s negligence. *Merrill v. Navegar, Inc.*, 28 P.3d 116, 124 (2001).

Strict liability differs from negligence in that it focuses on the design of the product rather than the conduct of the manufacturer. *Brown v. Super. Ct.*, 44 Cal. 3d 1049, 1056 (1988). Therefore, a plaintiff seeking recovery on a strict liability theory need not prove duty or breach of duty. *Brooks v. Eugene Burger Management Corp.*, 215 Cal. App. 3d 1611, 1625 (Cal. Ct. App. 1989). Instead, the plaintiff must show only that she suffered an injury and that a defect in the product caused the injury. *Id.* Generally, there are three types of defects that allow for recovery under a strict liability theory: manufacturing defects, design defects, and warning defects. *Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal. 3d 987, 995 (1991).

As to both theories, Plaintiff’s complaint fails to plead any of the aforementioned elements aside from the allegation that he suffered an injury to his eye. (Doc. 1-1 at 5). The complaint lacks any allegations of a defect in the vaccine, a failure to warn, what duty, if any, Defendant owed Plaintiff, and whether Defendant breached said duty. Accordingly, the Undersigned recommends dismissal of Plaintiff’s products liability claim because, as currently pleaded, it fails to state a claim upon which relief may be granted.

Leave to Amend

Generally, Rule 15 provides that “leave [to amend] shall be freely given when justice so requires.” Fed. R. Civ. P. 15(2). However, district courts are only required to grant leave to amend if a complaint can be saved. *Lopez v. Smith*, 203 F.3d 1122, 1129 (9th Cir. 2000). “Courts are not required to grant leave to amend if a complaint lacks merit entirely.” *Id.* When a complaint cannot be cured by additional facts, leave to amend need not be provided. *Doe v. United States*, 58 F.3d 494, 397 (9th Cir. 1995). Here, Plaintiff cannot cure at least two of the defects identified above. Specifically, Defendant is immune from Plaintiff’s claim under the PREP Act and the statute otherwise preempts Plaintiff’s claim. Accordingly, the Undersigned concludes that leave to amend

Plaintiff's complaint would be futile. *See, e.g., Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1039 (9th Cir. 2002).

Conclusion and Recommendations

For the reasons discussed above, the Undersigned RECOMMENDS that:

1. Defendant's motion to dismiss (Doc. 5) and request of the Court to take judicial notice (Doc. 6) be GRANTED;
2. Plaintiff's complaint (Doc. 1-1) be DISMISSED WITH PREJUDICE; and
3. The Clerk of Court be directed to close this case.

These findings and recommendations will be submitted to the United States district judge assigned to the case, pursuant to the provisions of 28 U.S.C. § 636(b)(1). Within 21 days after being served with these findings and recommendations, Plaintiff may file written objections with the Court. The document should be captioned "Objections to Magistrate Judge's Findings and Recommendations."

Failure to timely file objections may result in the waiver of rights on appeal. *Wilkerson v. Wheeler*, 772 F.3d 834, 839 (9th Cir. 2014) (citing *Baxter v. Sullivan*, 923 F.2d 1391, 1394 (9th Cir. 1991)).

IT IS SO ORDERED.

Dated: June 20, 2024


UNITED STATES MAGISTRATE JUDGE